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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,843	10/31/2003	Eric Hammill	279.581US1	9309

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EXAMINER

SMITH, STEPHANIE R

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/698,843	HAMMILL ET AL.	
	Examiner	Art Unit	
	Stephanie Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 14-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>20 September 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 14-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected method for measuring impedance, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 5, 2006.

Applicant's election with traverse of Group I, claims 1-13, in the reply filed on April 5, 2006 is acknowledged. The traversal is on the ground(s) that claim 11 constitutes a linking claim that must be examined with Group I and if allowable, requires rejoinder of Group II. This is not found persuasive because, as seen in claim 11, the means for detecting wear is disposed within the layer and is not measuring a second impedance or sending a signal if the impedance is in a range. In addition, claim 12 recites the means as a conductive sleeve, and therefore, claim 11 is not a linking claim since the means is part of the lead structure and not a measuring/monitoring unit.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on September 20, 2004 was filed after the mailing date of the application on October 31, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 2 and 13, "to a surrounding environment" is inferentially included and vague. It is unclear what the surrounding environment is. Everything is exposed to something that surrounds it. Further, it is suggested to positively recite or functionally recite the surrounding environment. If the Applicant wants to claim the surrounding environment, it is suggested to first positively recite the surrounding environment before it is used. If the surrounding environment is being functionally recited it is suggested to use "for" or "adapted to..."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2-6, 8, and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Verness et al (U.S. 6285910). Referring to claims 1 and 11-12, Verness et al. teach an implantable lead that includes a lead body with a proximal end, a distal end, and an insulating layer (see figure 1 and column 2, lines 49-51). The lead has a

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conductor disposed within the insulating layer and an electrode coupled to the lead body and in electrical communication with the conductor (see figures 6 and 7 and column 5, lines 33-49 and column 6, lines 7-19). The lead further has a conductive sleeve within the insulating layer that surrounds the conductor (see figure 15 and column 7, lines 57-61). While Verness et al. do not state the conductive sleeve has a first value in a first condition, it is known that all materials have a resistance to electricity in any given condition and therefore inherently has a first impedance before it is implanted. Referring to claim 2, in addition, it is noted that when the lead is implanted, the sleeve will have a second impedance value within a predetermined range since the inventors (Verness et al) determined beforehand that the sleeve will meet their needs for the lead (in the alternative, see the 103 rejection below). The predetermined range is the actual range of the sleeve while implanted. It is noted that the Applicant has not stated the numeric value at this range and that the ranges are different and what constitutes the surrounding environment. Regarding claim 3, Verness et al. teach that an opening extends from an outer surface of the insulating layer to expose the conductive sleeve to a surrounding environment (see figure 15), where the opening is the hole that extends longitudinally through the insulation, and is the end portion that fits into the connector that connects the lead to the implantable cardiac device, exposing the conductive sleeve not contained within the second conductive sleeve, such as the part of the sleeve that is crimped, to a surrounding environment. With regards to claim 4, the conductive sleeve extends through the lead body and is substantially aligned with a lead body longitudinal axis (see figure 15). Regarding claims 5-6, 8, and 13, the

second conductive sleeve is disposed within the insulating layer and surrounds the conductor and conductive sleeve, and further surrounds a second conductor (see figure 15 and column 7, lines 57-67 and column 8, lines 1-4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verness et al. in view of Jorgenson et al (U.S. 6317633). Referring to claim 2, Verness et al. teach that the conductive sleeve is exposed to a surrounding environment in a first condition, the first condition being defined as being surrounded by the second

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conducted sleeve, and the second condition being defined by the crimp sleeve not being surrounded by the second conductive sleeve (see figure 15). In both the first and second condition, the conductive sleeve has an impedance value as described above, and therefore, has a first and second impedance value, even if those values are the same. Jorgenson et al. do teach a system that periodically measures lead impedance values and compares them to upper and lower limits of a normal impedance range (see column 5, lines 66-67 and column 6, lines 1-5). Jorgenson et al. further teach that impedance is an indication of the integrity of the lead and that a lead condition can cause a failure to properly pace the heart (see column 3, lines 12-17). Regarding claim 3, Verness et al. teach that an opening extends from an outer surface of the insulating layer to expose the conductive sleeve to a surrounding environment (see figure 15), where the opening is the hole that extends longitudinally through the insulation, and is the end portion that fits into the connector that connects the lead to the implantable cardiac device, exposing the conductive sleeve not contained within the second conductive sleeve, such as the part of the sleeve that is crimped, to a surrounding environment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was disclosed to combine the lead system taught by Verness et al. with a predetermined range of impedance in order to ensure the integrity of the lead to properly pace the heart.

Claims 7, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verness et al. Verness et al. disclose the claimed invention but do not disclose expressly the insulating layer having three portions, where the conductive sleeve is

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interposed between the first and second portions and the second conductive sleeve is interposed between the second and third portions, the their portion surrounding the conductive sleeve. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead system taught by Verness et al. with the insulating layer having three portions, where the conductive sleeve is interposed between the first and second portions and the second conductive sleeve is interposed between the second and third portions, the their portion surrounding the conductive sleeve, because the Applicant has not disclosed that insulating layer having three portions, where the conductive sleeve is interposed between the first and second portions and the second conductive sleeve is interposed between the second and third portions, the their portion surrounding the conductive sleeve provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the first conductive sleeve extending through the insulating layer and the second conductive sleeve surrounding a portion of the first conductive sleeve as described above as taught by Verness et al, because it provides a means to measure the impedance of the lead and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Verness et al. Therefore, it would have been an obvious matter of design choice to modify Verness et al. to obtain the invention as specified in the claims.

Referring to claims 9 and 10, Verness et al. disclose the claimed invention except for the pulse generator and monitoring unit coupled with the lead assembly. It would

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have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead assembly as taught by Verness et al, with the pulse generator and monitoring unit coupled with the lead assembly since it was known in the art that the pulse generator and monitoring unit coupled with the lead assembly is used to provide therapy to the patient and to monitor the integrity of the leads.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. 2002/0058981 to Zhu et al. discloses a lead assembly that includes a partially insulated wire filament and a high impedance electrode that has an exposed surface.

U.S. 2002/0099430 to Verness discloses a lead having a cable conductor that has a safety cable if the primary cable fails. A change in impedance signals a potential conductor failure.

U.S. 4559951 to Dahl et al. disclose a catheter assembly that has conductors laterally offset from one another and buried between the walls of the tube.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Smith whose telephone number is 571-272-2834. The examiner can normally be reached on Monday-Friday between 7:30 am-4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SRS

GEORGE R. EVANISKO
PRIMARY EXAMINER

5/25/06